Patent
259.181

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Alison, et. al.,

Serial No.: Not yet assigned

Filed: Herewith

For: COMBINATIONS AND METHODS FOR PROMOTING IN VIVO LIVER CELL PROLIFERATION AND ENHANCING IN VIVO LIVER-DIRECTED GENE TRANSDUCTION

Group Art Unit: 1632

Examiner:

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449. Applicant respectfully requests that a copy of form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information, as defined in 37 CFR 1.56, exists.

The patents, publication and other information disclosed in the attached PTO Form 1449 were previously cited by or submitted to the Office in the following application which this application relies for an earlier filing date under 35 U.S.C. § 120: Application Serial No. 09/256,630 filed on February 23, 1999. Accordingly, pursuant to 37 CFR 1.98(d), copies of the previously cited or submitted patents, publications, and other information listed in the attached PTO Form 1449 are not attached.

INFORMATION DISCLOSURE STATEMENT FILING PROVISION:

☒ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

- ☒ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR §1.17(p) to the deposit account referenced below.
- ☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.

☐ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.

- ☐ The fee due under 37 CFR § 1.17(p) is submitted herewith.
- ☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

STATEMENT UNDER 37 CFR § 1.97(e):

☐ Each item contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.

☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:

☐ A check in the amount of _____ is enclosed for the above fee(s).

☐ Please charge _____ to Deposit Account No. **12-2475** for the above fee(s).

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Lyon & Lyon's Deposit Account No. **12-2475**.

Respectfully submitted,
LYON & LYON LLP

Dated: January 24, 2001

By: _____
Michael J. Wise
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FORM PTO-1449	ATTY. DOCKET NO.	SERIAL NO.
LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	259 181	
	APPLICANT: Malcom R. Alison; Charles Coutelle; Stuart J. Forbes; Humphrey J.F. Hodgson; Ildiko Sarosi; Michael Themis	
(Use several sheets if necessary)	FILING DATE:	GROUP:

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
	AA	5,650,504	07/22/97	Bartley, Timothy D., et al.			05/24/95
	AB	5,712,163	1/27/98	Parenteau, et al.			
	AC	5,716,934	02/10/98	Bartley, Timothy D., et al.			05/30/95
	AD	5,814,605	09/29/98	Pierce, Glenn Francis, et al.			06/06/95
	AE	5,824,303	10/20/98	Bartley, Tomothy D., et al.			05/19/95
	AF	5,824,643	10/20/98	Pierce, Glenn Francis, et al.			06/07/95
	AG	5,858,977	01/12/99	Aukerman, Sharon Lea			04/11/97
	AH	5,900,404	05/04/99	Gegg, Colin, et al.			08/15/97

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES	TRANSLATION NO
	AI	WO96/11949	4/25/96	PCT				
	AJ	WO96/11951	4/25/96	PCT				
	AK	WO98/24813	6/11/98	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

	AL	Andreadis, et al., Cell Cycle Dependence Of Retroviral Transduction: An Issue of overlapping time scales, Biotechnology and Bioengineering 58:272-281 (1998)
	AM	Angervo M, et al., Tri-iodothyronine and cycloheximide enhance insulin-like growth factor-binding protein-1 gene expression in human hepatoma cells, J. Mol. Endocrinol. 10(1):7-13 (1993)
	AN	Batshaw, Inborn errors of urea synthesis, Ann. Neurol. 35(2):133-141 (1994)
	AO	Bieniasz PD, et al., Cell cycle dependence of foamy retrovirus infection, J. Virol. 69(11):7295-9 (1995)
	AP	Bosch A, et al., Proliferation induced by keratinocyte growth factor enhances in vivo retroviral-mediated gene transfer to mouse hepatocytes, J. Clin. Invest. 98(12):2683-7 (1996)
	AQ	Bowling WM, et al., Portal branch occlusion safely facilitates in vivo retroviral vector transduction of rat liver, Hum. Gene Ther. 7(17):2113-21 (1996)
	AR	Branchereau S, et al., Factors influencing retroviral-mediated gene transfer into hepatocytes in vivo, Hum. Gene Ther. 5(7):803-8 (1994)

LA-173198.1 EXAMINER:	DATE CONSIDERED:

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant

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	AS	Canzanelli, et al., Control of liver regeneration and nucleic acid content by the thyroid: with the observations on the effects of pyrimidines, Am.J.Physiol. 157:225-229 (1949).
	AT	Cardoso, et al., In situ retrovirus-mediated gene transfer into dog liver, Human Gene Therapy 4:411-418 at 412 (1993)
	AU	Chang and Wu, Gene therapy: applications to the treatment of gastrointestinal and liver diseases, Gastroenterology 106:1076-1084 (1994)
	AV	Choo KH, et al., Molecular cloning of the gene for human anti-haemophilic factor IX, Nature. 299(5879):178-80 (1982)
	AW	Clarke DJ, et al., Genetic defects of the UDP-glucuronosyltransferase-1 (UGT1) gene that cause familial non-haemolytic unconjugated hyperbilirubinaemias, Clin. Chim. Acta 266(1):63-74 (1997)
	AX	Cosset FL, et al., High-titer packaging cells producing recombinant retroviruses resistant to human serum, J. Virol. 69(12):7430-6 (1995)
	AY	Demori I, et al., Tri-iodothyronine increases insulin-like growth factor binding protein-4 expression in rat hepatocytes, J. Endocrinol. 154(1):155-65 (1997)
	AZ	Davern, et al., Gene therapy for liver disease, Dig. Dis. 16:23-37 (1998)
	BA	Eisensmith & Woo, Somatic gene therapy for phenylketonuria and other hepatic deficiencies, J. Inher. Metab. Dis. 19:412-423 (1996)
	BB	Ferry N, et al., Retroviral-mediated gene transfer into hepatocytes in vivo, Proc. Nat'l Acad. Sci. U S A. 88(19):8377-81 (1991)
	BC	Ferry & Heard, Liver-directed gene transfer vectors, Human Gene Ther. 9:1975-1981 (1998)
	BD	Fisher, et al., Recombinant adeno-associated virus for muscle directed gene therapy, Nat. Med. 3:306-312 (1997)
	BE	Forbes and Hodgson, Review article: gene therapy in gastroenterology and hepatology, Aliment. Pharmacol. Ther. 11:823-836 (1997)
	BF	Forbes SJ, et al., Retroviral gene transfer to the liver in vivo during tri-iodothyronine induced hyperplasia, Gene Ther. 5(4):552-5 (1998)
	BG	Francavilla A, et al., Hepatocyte proliferation and gene expression induced by triiodothyronine in vivo and in vitro, Hepatology 20(5):1237-41 (1994)
	BH	Horsthemke B, et al., Identification of a deletion in the low density lipoprotein (LDL) receptor gene in a patient with familial hypercholesterolaemia, Hum. Genet. 71(1):75-8 (1985)
	BI	Horwich, Inherited hepatic enzyme defects as candidates for liver-directed gene therapy, Curr. Top. Microbiol. Immunol. 168:185-200 (1991)
	BJ	Housley RM, et al., Keratinocyte growth factor induces proliferation of hepatocytes and epithelial cells throughout the rat gastrointestinal tract, J. Clin. Invest. 94(5):1764-77 (1994)
	BK	Hudig F, et al., Tri-iodothyronine prevents the amiodarone-induced decrease in the expression of the liver low-density lipoprotein receptor gene, J. Endocrinol. 152(3):413-21 (1997)
	BL	Ill, Charles R. et al., Optimization of the human factor VIII complementary DNA expression plasmid for gene therapy of hemophilia A, Blood Coagulation and Fibrinolysis, Vol. 8, Suppl. 2, 1997
	BM	Kay, et al., Hepatic gene therapy: persistent expression of human alpha 1-antitrypsin in mice after direct gene delivery in vivo, Human Gene Therapy 3:641-647 at 642 (1992)
	BN	Kitraki E, et al., Hormonal control of insulin-like growth factor-II gene expression in the rat liver, J. Mol. Endocrinol. 9(2):131-6 (1992)
	BO	Knaan-Shanzer S, et al., Cell cycle state, response to hemopoietic growth factors and retroviral vector-mediated transduction of human hemopoietic stem cells, Gene Ther. 3(4):323-33 (1996)

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	BP	Kosai KI, et al., Retrovirus-mediated in vivo gene transfer in the replicating liver using recombinant hepatocyte growth factor without liver injury or partial hepatectomy, Hum. Gene Ther. 9(9):1293-301 (1998)
	BQ	Li, et al., In vivo gene therapy for hyperlipidemia: phenotypic correction in Watanabe rabbits by hepatic delivery of the rabbit LDL receptor gene, J. Clin. Invest. 95:768-773 (1995)
	BR	Lieber A, et al., Adenovirus-mediated urokinase gene transfer induces liver regeneration and allows for efficient retrovirus transduction of hepatocytes in vivo, Proc. Nat'l Acad. Sci. U S A. 92(13):6210-4 (1995)
	BS	Lieber A, et al., A modified urokinase plasminogen activator induces liver regeneration without bleeding, Hum. Gene Ther. 6(8):1029-37 (1995)
	BT	Mann, et al., Construction of a retrovirus packaging mutant and its use to produce helper-free defective retrovirus, Cell 33:153-159 (1983)
	BU	Oinonen T, et al., Hormonal regulation of the zonated expression of cytochrome P-450 3A in rat liver, Biochem. J. 309 (Pt 1):55-61 (1995)
	BV	Ott, et al., Simultaneous up-regulation of viral receptor expression and DNA synthesis is required for increasing efficiency of retroviral hepatic gene transfer. J. Biol. Chem. 273(19):11954-61 (1998)
	BW	Reich-Slotky R, et al., Chimeric molecules between keratinocyte growth factor and basic fibroblast growth factor define domains that confer receptor binding specificities, J. Biol. Chem. 270(50):29813-8 (1995)
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	BY	Roe, et al., Integration of murine leukemia virus DNA depends on mitosis, EMBO J. 12:2099-2108 (1993)
	BZ	Rusch, Sharyn L., et al., Protein transport via amino-terminal targeting sequences: common themes in diverse systems (Review), Molecular Membrane Biology 12, 295-307 (1995)
	CA	Sandig and Strauss, Liver-directed gene transfer and application to therapy, J. Mol. Med. 74:205-212 (1996)
	CB	Shima N, et al., Hepatocyte growth factor and its variant with a deletion of five amino acids are distinguishable in their biological activity and tertiary structure, Biochem. Biophys. Res. Commun. 200(2):808-15 (1994)
	CC	Stolz DB, et al., Comparative effects of hepatocyte growth factor and epidermal growth factor on motility, morphology, mitogenesis, and signal transduction of primary rat hepatocytes, J. Cell. Biochem. 55(4):445-64 (1994)
	CD	Strain AJ, et al., Native and recombinant human hepatocyte growth factors are highly potent promoters of DNA synthesis in both human and rat hepatocytes, J. Clin. Invest. 87(5):1853-7 (1991)
	CE	Von Heijne, Gunnar, Signal Sequences, The Limits of Variation, J. Mol. Biol. (1985) 184, 99-105
	CF	Zarnegar R, et al., Expression of hepatocyte growth factor mRNA in regenerating rat liver after partial hepatectomy, Biochem. Biophys. Res. Commun. 177(1):559-65 (1991)
	CG	Zhang, W.-W., Antisense oncogene and tumor suppressor gene therapy of cancer, J. Mol. Med. 74:191-204 (1996)

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	CH	Alberts, et al., Molecular Biology Of The Cell, 2d Edition, pp. 961-2.
	CI	Bosch, et al., Effects of keratinocyte and hepatocyte growth factor in vivo: implications for retrovirus-mediated gene transfer to liver, Hum Gene Ther 9(12):1747-54 (1998).
	CJ	Cabrera, et al., Targeted retroviral gene transfer into the rat biliary tract, Somat Cell Mol Genet. 22(1):21-9 (1996).
	CK	Cai et al.; "Therapeutic Levels of Human Protein C in Rats after Retroviral Vector-medicated Hepatic Gene Therapy"; ©The American Society for Clinical Investigation, Inc., Vol. 101, No. 12, June 1998, pp. 2831-2841
	CL	Crystal, R.G. Transfer of Genes to Humans: Early Lessons and Obstacles to Sucess. Science 270:404-410.
	CM	Deonarain, M.P. Ligand-targeted receptor-mediated vectors for gene delivery. Exp. Opin. Ther. Patents 8(1):53-69.
	CN	Forbes S J et al.; "Tri-iodothyronine and dHGF synergistically enhance hepatocyte DNA synthesis in vivo and enable peripheral venous strategies for retroviral gene transfer." HEPATOLOGY, vol. 28, no. 4 PART 2, October 1998 (1998-10), page 503A XP000946022; Biennial Scientific Meeting of the International Association for the Study of the Liver and the 49th Annual Meeting and Postgraduate Courses of the American Association for the Study of Liver Diseases; Chicago, Illinois, USA; November 4-10, 1998; ISSN: 0270-9139 abstract
	CO	Forbes S J et al.; "Retroviral gene transfer to the liver in vivo without prior partial hepatectomy." CLINICAL SCIENCE (London), vol. 94, no. 2, February 1998 (1998-02), page 2P XP000946045; Meeting of the Medical Research Society; London, England, UK; November 13-14, 1997; ISSN: 0143-5221 abstract
	CP	Forbes et al., Gastroenterology, Vol. 118, pages 591-598.
	CQ	Fujimoto, "Hepatology: Microcirculation and Pathogenesis of Alcoholic Liver Injury Gene therapy for liver cirrhosis"; Journal of Gastroenterology and Hepatology (2000) 1S (Suppl.) pp. D33-D36;
	CR	Gerolami et al.; "Evaluation of HSV-*tk* Gene Therapy in a Rat Model of Chemically Induced Hepatocellular Carcinoma by Intratumoral and Intrahepatic Artery Routes; Cancer Research February 15, 2000, Vol. 60, No. 4, pp. 779-1152
	CS	Grove et al., "Pre-clinical trials using hepatic gene delivery", Advanced Drug Delivery Reviews 30 (1998) pp. 199-204
	CT	Kolodka et al.; "Gene therapy for diabetes mellitus in rats by hepatic expression of insulin"; Proc. Natl. Acad. Sci. USA, Vol. 92, April 1995, Medical Sciences, pp. 3293-3297
	CU	Kalodka et al.; "Hepatic Gene Therapy: Efficient Retroviral-Mediated Gene Transfer into Rat Hepatocytes In Vivo"; Somatic Cell and Molecular Genetics, Vol. 19, No. 5, 1993, pp. 491-497
	CV	Le et al., "Therapeutic Levels of Functional Human Factor X in Rats After Retroviral-Mediated Hepatic Gene Therapy"; Blood, Vol. 89, No. 4 (February 15), pp. 1254-1259
	CW	Ledley et al.; "Retroviral gene transfer into primary hepatocytes: Implications for genetic therapy of liver-specific functions"; Proc. Natl. Acad. Sci. USA, Vol. 84, August 1987, Genetics, pp. 5335-5339
	CX	Lucey et al., "Minimal criteria for placement of adults on the liver transplant waiting list: a report of a national conference organized by the American Society of Transplant Physicians and the American Association for the Study of Liver Diseases"; Liver Transplantation and Surgery, Vol 3, 628-637
	CY	Miller et al. Targeted vectors for gene therapy. FASEB J. 9:190-199.
	CZ	Murphy, G.P. et al. American Cancer Society Textbook of Clinical Oncology, Second Edition. The American Cancer Society Inc., Atanta.

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	DA	Orkin, S.H. et al. Report and Recommendation of the Panel to Assess the NIH Investment in Research on Gene Therapy. National Institute of Health. Bethesda, Maryland.
	DB	Pakkanen, et al., Improved gene transfer efficiency in liver with vesicular stomatitis virus G-protein pseudotyped retrovirus after partial liver resection and thymidine kinase-ganciclovir pre-treatment, Pharmacol Res. 40(5):451-7 (1999).
	DC	Pakkanen, et al., Enhanced plasma cholesterol lowering effect of retrovirus-mediated LDL receptor gene transfer to WHHL rabbit liver after improved surgical technique and stimulation of hepatocyte proliferation by combined partial liver resection and thymidine kinase--ganciclovir treatment, Gene Ther. 6(1):34-41 (1999)
	DD	Qi et al.; "Blockade of type β transforming growth factor signaling prevents liver fibrosis and dysfunction in the rat"; Proc. Natl. Acad. Sci. USA, Vol. 96, March 1999, Medical Sciences, pp. 2345-2349
	DE	Remington's Pharmaceutical Services, Mack Publishing Company: Easton, PA, 18th Edition, pages 1303, 1304, and 1571.
	DF	Ruiz et al.; "Gene therapy of viral hepatitis and hepatocellular carcinoma"; Journal of Viral Hepatitis, 1999, 6, pp. 17-34
	DG	Themis M. et al. Enhanced in vitro and in vivo gene delivery using cationic agent completed retrovirus vectors, Gene Ther. 1998 Sept; 5(9):1180-6
	DH	Ueki et al., "Hepatocyte growth factor gene therapy of liver cirrhosis in rats": 1999 Nature America Inc., Vol. 5, No. 2, February 1999, pp. 226-230
	DI	Verma, I.M. et al. Gene therapy - promises, problems and prospects. Nature 389:239-242.

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